Organization, basically, the rules are stipulated that one country cannot arbitrarily refuse to import another country's product if it is not in consistency with that country's own safety standard.

So, in other words, if the United States had a safety standard, but for one reason or another did not want to import something, some product that was coming from the European Union, we could not fabricate some reason why that particular production should not be allowed into the United States, if it met our safety standards.

And, obviously, we do have some issues with the World Trade Organization regarding veterinary drug residues between the European Union and the United States, and we have used the World Trade Organization in order to try and resolve some of those disputes. But that is basically what the function of that is.

So, for the European Union, again, I think we are fairly similar. It is where we get into some of the issues of countries that may not be as technically advanced as the United States or the European Union, where they have diseases that did not occur in the more tempered regions of the world.

But, yet, they definitely have the need for drugs to treat some of these diseases. Trypanosomiasis

is a classic example of a disease that does not occur in the tempered areas, but which is an absolute critical disease to control in more tropical climates.

It is in those countries where we would have more concerns about the quality of the data that were used to approve those drugs.

DR. LANGSTON: Everyone ready to move on to question 2?

(Question 2)

DR. SUNDLOF: Okay. Question 2 reads, just we will read the issue:

"The tolerance established by FDA for a new animal drug approved under Section 512(b)(1) of the Act is based on data submitted by the sponsor. These data are owned by the sponsor of the pharmaceutical company, producer, organization, et cetera, that paid for the study, and is accountable for the quality of the research.

Each subsequent sponsor seeking approval of the drug under Section 512(b)(1) of the Act must submit similar human food safety data as required to support the tolerance for their product. Each new animal drug tolerance is established for each drug product rather than the drug substance or active ingredient.

However, the Animal Drug Availability Act

allows for data for an import tolerance to include data submitted by the manufacturer to the appropriate regulatory authority in any country where the new animal drug is lawfully used or data available from a relevant international organization. Any country wanting its producers to become eligible to export to the United States could be a sponsor of an import tolerance."

So, based on that information, the question reads:

"Only the drug marker residue or the drug substance, not the product formulation, or the sponsor of the import tolerance can be determined by the type of analytical method that is typically used to assay imports.

Are there analytical techniques or other approaches that would allow us to determine whether a residue is due to the use of the drug product for which the tolerance is approved?"

DR. LANGSTON: I need some clarification here. I thought earlier it was said that there was only one tolerance set for a product. And this is saying it is a formulation tolerance. Could you explain the difference?

DR. SUNDLOF: Right, we calculate the tolerance for each individual formulation for the drug.

But, somehow, it all comes out to be the same number. I better get some residue folks to help me out with this one.

But, generally, we look at the different formulations. Remember, we do have considerable safety factors involved. We try and make sure that whatever tolerance that we do set is sufficiently robust to take into account the various other formulations.

So the tolerance is a relatively conservative estimate. If there are slight differences in the data from the various formulations, that pretty much gets taken into account. Dr. Robinson.

DR. ROBINSON: To clarify, if you look at 21 CFR 556, the tolerances specified in there are for drug substances, principally, for the active ingredients. A drug product has to go through the full examination, particularly, a pioneer product, has to go through the full examination.

And if there is another pioneer product with the same active ingredient that has been previously approved, we still have to go through the process to make sure that the previously established tolerance is the same for the new drug product. So far, we have had no situation in which there has been a tremendous degree of deviation.

But, in theoretical case that there were, due to a formulation change that for some reason changed the pharmacokinetics or dynamics of the drug; then if that tolerance was lower for the new drug product, the existing pioneer would also get the new lowered tolerance. Okay?

DR. HASCHEK-HOCK: Well, first of all, I think that there should not be a difference between what is accepted for domestic use, domestic tolerance and international tolerance. But does that mean that, perhaps, we do not need to look at formulation for domestic use?

I do not know the answer to that question. Theoretically, of course, as indicated, there could be marked differences. But I think the main thing is that both are treated equally, at least in my opinion.

DR. KOCHEVAR: Have there ever been instances where they were different, markedly different?

You said you thought most of the time they were the same. Have there ever been cases where, in fact, you did end up lowering a tolerance because a second product was different?

DR. ROBINSON: I think that Dr. Weber could probably speak to that better than I historically. What I am aware of is that a different formulation has in, at

least one particular instance, caused us to adopt an additional tolerance, additional type of tolerance than what was already on the books for that active ingredient. And, in that case, it had to do with the route of administration. So I am not sure. Dr. Weber.

DR. WEBER: That is accurate. What we have looked at in the past is make sure, especially where you might see, likely to see differences, is oral versus parenteral, where you get first past effect and things from liver.

You want to be certain that one route is not inconsistent with the other in terms of what has been tested. In most of those instances that I am aware of, we often had the oral route first, which gave them more complex metabolism, which dealt with the metabolism issue.

It also wound up with a smaller proportion perhaps of marker residue, when you went to a parenteral route, a different formulation or substance, you saw a simpler situation, where the marker might have been higher. But we stayed with the more conservative of the two.

What we have affirmed is that the change in formulation was not sufficient to -- that we have taken into account, that it is not inconsistent with a profile

that we have seen before, or the number we selected for the marker.

DR. HASCHEK-HOCK: So what you are saying then is that practically it is mainly the route of administration. The change in formulation is because of a change in the route of administration, and is probably the route of administration that makes the difference.

DR. WEBER: That is where we see the larger differences because of the liver versus non-first pass effects.

DR. MACDONALD: The differences on a solution or an injectable are negligible. On a solid dosage form, however, the concerns can be quite great on the preparation of the basic drug substance itself.

This is of great concern on the human side that the absorption studies that you do have product defined in terms of crystal structure. The presence of other crystal forms will greatly affect the dissolution rate and the absorption rate.

On the human side of developing products, almost very, very early in the game, you have to define the crystal form that you are going to use for oral studies to define your absorption.

The crystal form can range from a non-crystal and a morphous form, which is usually the most soluble,

with the best absorption to various crystal forms with lesser absorption. The issue of the different structure, the polymorphs, is a critical aspect on the human side.

And, while it has not been emphasized, in the early days on the veterinary side it certainly is a concern today that your product has the same crystal form and the same dissolution characteristics. And, therefore, the absorption characteristics. That is an integral part of the work up these days. So this question of manufacturing does play a role.

DR. HOLLAND: What are the ramifications of a country being a sponsor of an import tolerance?

DR. SUNDLOF: Well, the country would have to provide the quality of data that we would accept from a drug manufacturer's sponsor in the United States. So they would basically have to meet the same criteria that any drug sponsor would be required to provide us.

That means, generally, that they are going to have to work with the drug companies sponsors in order to convince them to provide the information to us, so that we can establish an import tolerance.

DR. HOLLAND: So it goes back to the pharmaceutical company?

DR. SUNDLOF: Yes, and some of the

difficulties with that are that, again, when we look to less developed countries, they may not have access to those data. They may be using generic substitutes that never had to provide that kind of information.

So the responsibility or the onus on the country to provide those kinds of information is relatively steep, and we see this extensively in the Codex Alimentarius process, where developing countries are in desperate need to get Codex MRLs, so that they can export their food products to other countries.

And, in many cases, they are not ever able to obtain the kind of quality of information that would allow the JECFA in this instance to establish an MRL.

DR. HOLLAND: Well, wouldn't this have some profound effects on national versus multinational companies?

DR. SUNDLOF: Well, again, the data are generally considered proprietary to the company, whether it is national or multinational. And it is my sense that the country requesting the import tolerance would not be able to compel the company to provide the information if they decided that they did not want to.

Now, that may be subject to various laws in various countries, but my sense is that they would somehow have to rely on the good graces of the

pharmaceutical firms to provide the data.

DR. LANGSTON: Let me propose some options for this -- for your consideration. I have just kind of been taking notes here, things that people have said, and I have considered, to tell a formulation.

One possibility might be a tracer within that substance, an excipient, a vehicle, et cetera, such as someone brought up in a discussion, just benzothene penicillin versus procaine.

If you did have different tolerances set, which is unlikely at this point, but if you did have different tolerances for the two products, you could possibly assay for either benzothene or procaine. That would be one option.

The other option would be isomeric differences. I will defer to Dr. MacDonald or others. I understand that is quite difficult to do, but possible I suppose.

And the third would be possibly metabolic profiles, which we mentioned, where you are looking at metabolic ratios. If it goes through an oral route, it might have a higher metabolic ratio to parent compound. I would suspect that if it is a similar product and route, you would not see a difference. But if it is a different formulation and different route and/or

different route, you might see that.

So any comments on either of those three options, or any additional options to come up with an answer for the question?

DR. HASCHEK-HOCK: Question. Are stereoisomers screened for in domestic drug approval?

DR. MACDONALD: Yes, absolutely. I think that today's world, early in the game you have to specify the stereochemistry. Racemic mixtures are just not acceptable anymore. And, not only that, you have to -- the crystal form is extraordinarily important.

DR. LANGSTON: How likely do you think it would be that you could differentiate a formulation based on differences?

DR. MACDONALD: The crystal form issue is -- usually, you see that pretty quickly on a blood curve, if there are differences. The first thing you would do, you look at it in terms of dissolution. Are there any major changes on dissolution?

There is an whole array of tests that you can do on crystal form starting with x-ray crystallography, and then looking at characteristics, behavior characteristics. But, yes, you can certainly distinguish between the two.

This is something, however, you know, that the

animal drug industry lags the human drug industry considerably, and there are not that many new drugs starting off in the animal site. So I do not even know whether this is truly an issue in terms of development.

I have a tendency to use a morphous material because you get the best availability, and it is easy to do, and et cetera.

In terms of having an analytical method that could distinguish your particular product on an isotopic ratio business, looking at the ratio of C12 and C13, that is something you might have a shot at on a bulk substance, but at a residue level that would be very, very hard.

DR. LANGSTON: I will comment personally on the tracer issue. I threw that out for food for thought, but I kind of doubt it would be the case. You would have to have something in the compound that had at least the same or similar half life as the parent compound on metabolite. That would be difficult to come up with.

And then if you added something beyond that, you are really adding another substance to the -- that you have to do toxicity testing on. So I tend to discount my own suggestion, for what it is worth.

Any other comments on question 2, additional

methods to address, how to detect a different formulation?

Let's go to question 3 then.

(No response)

(Question 3)

DR. SUNDLOF: Okay. The issue underlying question 3 is, we are considering how we should inform the public of the import tolerance process while also ensuring that we do not disclose trade secrets and confidential commercial information.

So the questions are -- there is four of them. Should we disclose to the public that we considering an import tolerance for a new animal drug?

And, if the answer to that is yes, then when upon request upon filing?

C. How should we do so, federal register, the internet?

D. How much detail should we provide keeping in mind that we cannot disclose trade secrets or confidential commercial information?

DR. GLENN: It seems like this should be consistent with the new animal drug approval process.

DR. KOCHEVAR: Just to play the devil's advocate, isn't it a little different though, because that is a new drug, it is a process by which, you know,

new efficacy data and data on a number of other things is presented, whereas, these are drugs that are already approved somewhere?

And so, they are already in the public domain some place or else they would not be coming to this country for an import tolerance.

So, in some sense, it makes sense that if there were a component of this country that did not want a drug to be in their food chain, then the earlier they knew that, the more likely they would be to be able to be involved in that approval process.

Whether that is a good thing or a bad thing, I do not know, but that would be the argument for putting it up earlier rather than later.

DR. HASCHEK-HOCK: I guess I have not really heard any good reasons. Now you mentioned one about perhaps not wanting to get in the food chain, but I have not heard any really strong reasons for actually disclosing it early.

It would seem that it would add -- I would assume that many of the drugs that would probably be -- request approval would not get the approval just because the data was not available. And so, that might be a lot more work. But if there are strong reasons for having it released earlier, I would like to.

DR. WOOD: I would not argue necessarily for it to be early disclosure, but I do think that disclosure to the public does need to happen. But in thinking about this and hearing some of the presentations today, I think it needs to be offered in a way where then the public has a way to respond, as opposed to simply announcing that this tolerance level is being considered or has been considered. Anne, thank you very much.

But there needs to be a format for which there could be a response. And so, in my mind that would mean perhaps then the option of it being published in the federal register with 90, 120 days, or a year for public comment before the issue was finally established.

And, in that regard, with question C, working with a number of groups, as we all do, only a few of which love to go to sleep reading the federal register at night, I think it is important that it published in the federal register because that is the official document of government by which things move forward.

But I think it is equally important that, at the same time, it be placed on the internet. I do know people with groups with whom I work that actually go to the CVM site at times every day to see what is new, and to monitor and follow developments on issues that are of

importance to that group, so a combination of federal register with internet publication.

And, again, the notice happening at an appropriate time, not early in the process, perhaps, when the decision has yet to be made, but at some timely point where then there is an opportunity for the public to respond, and for then there to be final action by the agency.

DR. HOLLAND: How difficult would it be to collect historical use in some of these compounds in other countries and have that part of the document?

DR. SUNDLOF: I cannot answer your question. It may be very difficult. It may not be difficult at all. It is certainly something we could address.

If the committee felt that that would be important information to accompany any public announcement that FDA is considering establishing an import tolerance for drug X, and then have, in addition to that, some background information about this drug has been used in these countries for X numbers of years.

Is that the kind of thing that you are talking about?

DR. HOLLAND: Yes, and adverse effects, if any, that kind of information.

DR. SUNDLOF: I think that is something that

the committee could recommend.

DR. KOCHEVAR: I think you made a really good suggestion, just some sort of provisional approval, where you have a comment period would be, you know, I think a good compromise.

DR. HASCHEK-HOCK: The documentation that is provided in apparently what the EPA has decided is that they would -- if the tolerance limit differs from the accepted international level, then there would be information as to why a different tolerance level was set.

And I think that that probably, at that time, that might be a good place to indicate if there are special issues that cause the tolerance limits to be set. And that might address how much detail should we provide, would seem like the information that Dr. Holland suggested, and also any special considerations might be the things that should be released at that time.

DR. CARSON: That is what I was going to ask Richard, how specific information would be generic in nature that would be available or -- I like the idea too of some early notice. But I am just wondering how specific could you get without any proprietary problems there.

DR. WOOD: That one I may need a night to sleep on. But I would think certainly, I mean, the concern is the matter of public health. So information that would be pursuant to what kinds of impact it has on public health, what kinds of -- what has been the experience in relationship to that residue in terms of public health would be the most important thing. So I would not think that those kinds of questions would be proprietary.

DR. KOCHEVAR: I think interested parties would be very capable, especially on the internet, of finding information rather rapidly on a substance. I mean, it was not proprietary once they had the name of it.

DR. GLENN: I need some clarification on this, as regards to the current activity within an NADA. I took notes here. FDA does not think disclosing information early is important to public health.

Is there a new blueprint for expansion of this concept? And, Steve, are we adopting this into various new things in an integrated way, you know, step-wise or -- and why would we do it here?

You know, I am just wondering if there is any negative consequences for doing it in this situation like alarming the public or something, as opposed to a

new animal drug application.

DR. SUNDLOF: I think we are pretty much constrained in the new animal drug application, as to what we can disclose and when. I do not think we have the same imposed constraints with this process, where the committee is asking for advice. If you had it to do all over again, would you disclose this information earlier, in the interest of public's right to know?

One other thing, as long as I have got the floor here, with any of our NADAs, once we approve them, we have a freedom of information package that goes with it and it outlines the basis for our decision on what the tolerance should be.

So it does not give specific data, but it does summarize the data that were used in saying why we came out the way we did.

Now, I presume that we would do the same kind of thing if we were setting an import tolerance, in which there would be some kind of freedom of information statement that went out with it, that basically disclosed the basis on which we established the tolerance.

DR. GLENN: I do not have a problem with transparency of the public.

DR. KOCHEVAR: I think communicating with the

public is one of the things we need to do very well. But I just wanted to understand if there were ramifications on the current activity of the agency.

And, you know, you say, well, we are doing it here, but you are not doing it there, and I do not know what implications that might have. It seems like maybe the one difference there is what you were getting at, and that is there is a history to these drugs; whereas,. there are no histories really to the NADAs.

DR. LANGSTON: Also, we have the full regulatory process looking at this whole drug from start to finish here, and we do not have control over that in a foreign country necessarily, would be another factor.

Any other comments?

(No response)

DR. LANGSTON: Okay, issue number 4.

DR. SUNDLOF: Okay. Issue number 4, we are just seeking advice. So I guess there is not a specific question here. It says:

"We are considering amending the regulations at 21 CFR 25.33, to allow a categorical exclusion for import tolerances under the National Environmental Policy Act, if there is information that shows that establishing import tolerance does not have a significant effect on the environment. We are seeking

information on whether import tolerances will have a significant impact on the environment or effect on the environment."

DR. HASCHEK-HOCK: (Away from mike) I assume you referred to ---.

DR. SUNDLOF: I think that is how -- that was the intent under which this was written and not the effects on the environment of the country that would be importing animal products.

DR. KOCHEVAR: What is the basis now for excluding most drugs from environmental impact studies?

DR. SUNDLOF: They were listed earlier. But, basically, if we consider that the use would be insignificant to cause an environmental hazard.

DR. KOCHEVAR: Okay. So there is not an elaborate process. It is just --

DR. SUNDLOF: Oh, it is a pretty elaborate process.

DR. KOCHEVAR: To be able to get it excluded, it is an elaborate process?

DR. SUNDLOF: The company basically has to make a solid case as to how much they believe is going to go into the environment. In the human drug areas, there is a cut off limit that you would expect less than -- and I cannot remember if it is one part per billion,

or 10 parts per billion, or something along those lines.

But if you expect that the concentration in the environment would not exceed some cut off level, that that would qualify companies for a waiver for doing an environmental study. There is a number of issues that we look at.

For instance, our drugs is going to be used in environmentally sensitive areas like in aquatic environments. Are they going to be used in CFOs, these concentrated animal feeding operations, where there may be a lot of the drug -- you know, a substantial quantities of the drug being used?

And so, you have a very point, you know, concentrated point source where there might be environmental damage as the result of the drug itself versus situations where the drug is going to be administered by a veterinarian during the course of his practice on an animal-by-animal basis, where you would expect very little environmental damage.

So, a lot of these issues get weighed. And, depending upon the final analysis of all of those different criteria, the company either is granted a waiver, or they are not. And they are required to provide some environmental impact data that can be substantial thousands of pages. And so, it is highly

variable. In this case, the drug is not going to actually be used in the United States.

DR. HASCHEK-HOCK: Given that only edible tissue would be imported, are there any associated issues with environmental spread of the compound? It would seem that there would be none or negligible.

DR. LANGSTON: I cannot think of any.

DR. WOOD: We are done with that one.

DR. LANGSTON: All opposed?

(No response)

DR. SUNDLOF: Okay. Then I assume, Mr. Chairman, that we are done with issue number 4?

DR. LANGSTON: Yes.

DR. SUNDLOF: Okay. Then issue number 5 is please comment on any other aspects of import tolerances you may wish to raise. And I think we already heard one.

DR. LANGSTON: I would just emphasize that we certainly have heard those about unfair practices or competitive disadvantages, these sorts of things. I think that is fair to include. Does anyone have anything else along those same lines?

DR. KOCHEVAR: I guess I would just have a question, and it kind of came up earlier. We are going to have some discussions in the next couple of days

about antimicrobial resistance, and how much impact, or how much discussion will be had by the public at large if now antimicrobial that are not approved in this country are entering our systems.

It is true they are not entering the systems of animals that will excrete them and have resistance coliforms, and so on, and so on. But how much of an issue is that for public health concern?

I mean, you know, it will now be in our GI tracks, and is that a significant issue?

DR. WOOD: I would like to keep it on the table in some way -- I mean, if only as an emerging question that would be before us and before CVM as they develop policies dealing with antimicrobial approvals for new approvals in the U.S. I think that companion aspect of that needs to be looking at what kinds of impact does that have on import tolerances as well.

DR. ANDERSON: I agree. And also, I just wanted to be clear. I am not certain that we are only talking about antibiotics that go into the human intestine, because I thought in the aquaculture talk that he had said that part of the import is in fish meal.

So couldn't that be given to animals, and then we have antibiotics that are being given to animals and

residues could be excreted into the environment?

DR. KOCHEVAR: So I did not get that. So we are talking on import tolerances could actually be drugs that are not approved in this country that are present at some level and substances that will then be fed to animals?

DR. SUNDLOF: Alicia raises a valid point, but it is separate from the import tolerance issue. Just to bring people up to speed, there happens to be an issue in Europe in the European Union right now in which they have traced chloramphenicol residues back to shrimp meal.

Obviously, shrimp meal that came from a country probably, we would guess probably -- and I should not guess. So I am not going to same where it might have come from.

But I think that would -- I mean there should not be drugs unless they are specifically added to feeds. And if we found a feeding substance that contained antibiotics or other animal drugs, that would not be considered fit for animal feed. I mean it just would not.

We do not need any new regulations on that unless somebody -- if somebody wants to import feed that contains specific medications, they would have to go

through the new animal drug approval process. They do not get by on an import tolerance.

DR. LANGSTON: Any other comments?

DR. WOOD: Back on the first one that you raised, and that Deborah raised earlier on banned substances, and how to handle. For me, that is not just a question of being fair to the industry, I guess, but it is also a question of protecting human health.

And I do not know if that is really an appropriate way to handle it here, and it may be more of an enforcement question. But, I mean, the reason why a number of these substances were banned was because of the findings of the FDA that they did have a negative impact on human health or detrimental to human health.

And, yet, we are saying there simply needs to be a zero tolerance. You can use it with your animal, but when we are importing it there is going to be a zero tolerance.

Out of my own feeling of, I guess, skepticism, we trust that all of the drugs residues that are illegal are being caught as they come into our borders. But I am sure that is probably not always the case.

And though we have to allow that to happen in areas where tolerances have been established, to allow a tolerance to be established on -- even a zero tolerance

to be established on a drug that is banned, in a way to me, opens the door to placing human health in the U.S. at risk.

I would rather that we not do that, perhaps, because of trade questions we are not able to ban or place -- or to ban a substance on those terms, but it certainly is a concern to me.

DR. PARKHURST: I would have to second that, and I think it is an issue of, is there equipment good enough to detect that zero level? Because the zero level could fall getting more sophisticated equipment. And if somebody has decided that it is banned, I mean, enough work has been done, that that is an issue. And I think it would be almost falling down on our job to let it go through.

DR. WAGES: I agree in principle, but we have got to remember that there is an import and there is an export, and countries will use a potential ban that we have and impact our exporting abilities because of, I'll say, foo foo dust.

The things that are of concern raised for diseases, et cetera, that have no implications on human health and still can ban our products. I agree with you. I mean, I think my gut reaction is it not good enough for our animals, and there has been a concern

from a public health standpoint why they were removed.

There is no way that I would support continuing to import food that has been fed that, but it is a two-way street. We need to be careful before we recommend.

DR. LANGSTON: I would also point out that these drugs were banned for potential public health impact. I am not aware of any proven public health impact on these. That is not to say they could not occur, and that is obviously why the FDA banned them.

You can get into issues of whether you believe that or you do not, but for me it is a bigger issue relative to being fair to the producers, notwithstanding that perhaps it is an issue for some people.

DR. GLENN: So just wait until we do public disclosure of that particular issue.

DR. KOCHEVAR: So how would it work though if you were going to say we just, for whatever reason, decide it is not acceptable to import food substances from countries that say it is okay to use, for example, chloramphenicol, even though we are going to have a zero tolerance?

What would be the alternative? Do we say to those countries, if you have a producer who wants to import food to this country, they must be certified as

not using these drugs on their -- you know, in their operation?

I mean, what alternatives would you have? Because we cannot really dictate what country X wants to ban, in terms of their drugs. But is there some in between ground that would make that feasible?

DR. SUNDLOF: Yes, I think there is. And, certainly, under the World Trade Organization, we have set a standard, a safety standard for our country that says any use of this particular drug is inherently subjects our population to a greater risk than we think is acceptable.

We could make the case, since that is our standard, we have set a specific safety standard for our public; that we could make the case that any country that wanted to import, did not meet our standards, and we would probably be sustained. Our position would be sustained in the World Trade Organization.

So I think we have that capability to do that, but there may be other ways to get around that if we have some kind of adequate assurance that any products were imported in the United States were not exposed to that particular drug. I think there is probably several different options that could be used.

DR. LANGSTON: Any other comments?

(No response)

DR. LANGSTON: Just a reminder then, I am sure there will be a few procedural comments after this. But we will start off first thing in the morning going through these questions, asking each of you for your opinions on them. It won't be a formal vote, per se, but we will be collecting your views on the issues.

DR. WOOD: And then you will be summarizing where the committee stands as a recommendation? I mean, what goes to Dr. Sundlof then following tomorrow's responses?

DR. LANGSTON: Dr. Sundlof.

DR. SUNDLOF: We would like to get the consensus of what the committee's decisions are. So, hopefully, you will be able to have your answers somewhat sketched out so that we can go back and say this is what the committee recommended to us on each of those.

DR. LANGSTON: I will try to put together a summary with input from the committee.

DR. SUNDLOF: Okay. Mr. Chairman, I turn the meeting back over to you.

DR. LANGSTON: Okay. Are there any other issues?

(No response)

DR. LANGSTON: In that case, we will adjourn until 8:30 in the morning.

(Whereupon, the meeting was adjourned at 4:24 p.m.)